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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/435,770	11/08/1999	TAKUO YAMAMOTO	YAMAMOTO=16A	5666

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/435,770	Applicant(s) YAMAMOTO ET AL.	
	Examiner Christian L. Fronda	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-64 and 66-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60-64 and 66-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 November 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 60-64 and 66-74 are pending and under consideration in this Office Action.
2. The rejection of claims 59 and 65-70 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement has been withdrawn in view of applicants' amendment to the claims filed 10/31/2005 and applicants' submission of the **DECLARATION OF BIOLOGICAL MATERIAL DEPOSIT** dated 10/31/2005 for the microorganisms recited identified by accession number FERM BP-6450.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 60, 61, 66-70, 72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
Claims 60 recites the phrase "a purified non-reducing saccharide-forming enzyme which is a non-reducing saccharide" renders the claim vague and indefinite. It is not clear if applicants actually intended to recite a purified non-reducing saccharide-forming enzyme which **forms** a non-reducing saccharide having a trehalose structure as an end unit.
Claims 61, 66-70 which depend from claim 60 are also rejected because they do not correct the defect of claim 60. Appropriate correction is requested

Claims 67, 72 recites the phrase "derived from a microorganism" renders the claim vague and indefinite because it is not clear if the claimed enzyme is obtained and isolated from a microorganism or if the claimed enzyme is a mutant or variant of the enzyme recited in claim 60. Amending the claims to recite that the claimed enzyme is isolated from the microorganism may overcome the rejection.

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Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 62, 63, 64, 69, 70, 71, 73, 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 62, 63, 64, 71 are genus claims that are directed toward a genus of any fragments of SEQ ID NO: 1. The scope of the genus includes many members with widely differing structural, chemical, and physiochemical properties including widely differing amino acid sequences and biological functions. Furthermore, the genus is highly variable because a significant number of structural differences between genus members exists.

The specification discloses a non-reducing saccharide-forming enzyme from *Arthrobacter* sp. S34 (FERM BP-6450) that consists of the amino acid sequence of SEQ ID NO: 1, where said enzyme forms a non-reducing saccharide having a trehalose structure as an end unit from a reducing partial starch hydrolysate.

The claim as written, however, do not recite any particular structure to function/activity relationship that clarify what common attributes are shared by members of the claimed genus. Thus, one skilled in the art cannot visualize or recognize the identity of the members of the claimed genus of fragments of SEQ ID NO: 1.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definitions, such as the structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe the genus of genetic materials, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g. structure, physical and/or

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chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. Therefore, the instant claims are not adequately described.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of a genus of any fragments of SEQ ID NO: 1.

Amending the claims to recite that the claimed fragments has the activity of forming a non-reducing saccharide having a trehalose structure as an end unit from a reducing partial starch hydrolysate may overcome the rejection.

In regard to claims 69, 70, and 73 the claims encompass a genus of mutants and variants of *Arthrobacter* sp. S34 (FERM BP-6450). The specification discloses a non-reducing saccharide-forming enzyme of SEQ ID NO: 1 was isolated from *Arthrobacter* sp. S34 (FERM BP-6450), where said enzyme forms a non-reducing saccharide having a trehalose structure as an end unit from a reducing partial starch hydrolysate. However, there is no disclosure of any biological characteristics of the mutants and variants of *Arthrobacter* sp. S34 (FERM BP-6450) for which one skilled in the art can visualize or recognize other members of the claimed genus. In view of these considerations, one of skill in the art would not recognize that applicants were in possession of a genus of mutants and variants of *Arthrobacter* sp. S34 (FERM BP-6450).

Amending the claims by deleting the phrase "and mutants thereof" may overcome the rejection.

In the evaluation of new claim 74 for compliance with the written description requirement of 35 U.S.C. 112, of particular relevance is 66 FR 1099, Friday, January 5, 2001, which states:

"*Eli Lilly* explains that a chemical compound's name does not necessarily convey a written description of the named chemical compound, particularly when a genus of compounds is claimed. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1405. The name, if it does no more than distinguish the claimed genus from all others by function, does not satisfy the written description requirement because "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Thus *Eli Lilly* identified a set of circumstances in which the words of the claim did not, without more, adequately convey to others that applicants had possession of what they claimed." (see p. 1100, 1st column, line 47 to 2nd column, line 2).

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Claim 74 is drawn to a genus of non-reducing saccharide-forming enzymes, and mutants and variants thereof. The scope of the genus includes many members with widely differing structural, chemical, and physiochemical properties including widely differing amino acid sequences. Furthermore, the genus is highly variable because a significant number of structural differences between genus members exists.

The specification discloses a non-reducing saccharide-forming enzyme isolated from *Arthrobacter* sp. S34 (FERM BP-6450) that consists of 756 amino acids as shown in the amino acid sequence of SEQ ID NO: 1, where said enzyme forms a non-reducing saccharide having a trehalose structure as an end unit from a reducing partial starch hydrolysate. However, the recitation of "non-reducing saccharide-forming enzyme" does not define any structural features and amino acid sequences commonly possessed by the genus. Furthermore, the specification does not describe and define any structural features and amino acid sequences commonly possessed by the genus. Thus, one skilled in the art cannot visualize or recognize the identity of the members of each genus for use in the claimed method.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of a genus of non-reducing saccharide-forming enzymes, and mutants and variants thereof.

Amending the claim to recite the specific SEQ ID NO of the amino acid sequence of the enzyme may overcome the rejection.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 74 is rejected under 35 U.S.C. 102(b) as being anticipated by Nakada et al. (Biosci Biotechnol Biochem. 1995 Dec;59(12):2215-8 (ABSTRACT)).

Nakada et al. teach a maltooligosyl trehalose trehalohydrolase isolated from *Arthrobacter* sp. Q36 which forms a non-reducing saccharide having a trehalose structure as an end unit, has a molecular mass of 62,000 by SDS-polyacrylamide gel electrophoresis, has a pI of 4.1 by gel isoelectrofocusing, and has pH stability from pH 5.0 to 10.0 (see Abstract). The examiner takes

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the position that the approximate molecular weight of the taught maltooligosyl trehalose trehalohydrolase falls within the range of 62,000 +/- 5,000 because this particular margin of error is known to be inherent in SDS-polyacrylamide gel electrophoresis analysis.

Since the maltooligosyl trehalose trehalohydrolase taught by Nakada et al. is isolated from *Arthrobacter* as the claimed enzyme, has the same activity as the claimed enzyme, has the a molecular weight that would fall within the recited range, has a pI that falls within the claimed range, has a pH stability from pH 5.0 to 10.0, has a pH optimum of about 6.5 which falls within the claimed pH range, then the taught maltooligosyl trehalose trehalohydrolase anticipates the recited enzyme.

Since the Patent Office does not have the facilities for examining and comparing the maltooligosyl trehalose trehalohydrolase taught by Nakada et al. to enzyme recited in claim 74, the burden is on applicant to show that the maltooligosyl trehalose trehalohydrolase taught by Nakada et al. is different from the claimed enzyme which forms a non-reducing saccharide having a trehalose structure. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

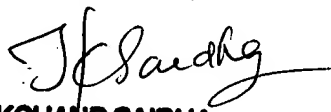
Conclusion

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).
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PRIMARY EXAMINER